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UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

#11

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,199,569, was filed on January 8, 1997, under 35 U.S.C. § 156. U.S. Patent No. 4,199,569 issued on April 22, 1980 from an application that claimed priority under 35 U.S.C. § 120 to an application that was filed on October 3, 1977. Accordingly, the original expiration date of the patent is October 3, 1997.

The assistance of your Office is requested in confirming that the product identified in the application, STROMEKTOL® (ivermectin), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, processing of the application cannot be completed before the patent is due to expire, October 3, 1997. Accordingly, should you confirm that the product has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was timely filed, an interim extension under 35 U.S.C. § 156(e)(2) will be granted to provide sufficient time for processing of the application to be completed.

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.



Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Project

cc: David L. Rose
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